UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

JEANINE A. SORTISIO,
STEVEN R. SORTISIO,

Plaintiffs,

Hon. Hugh B. Scott

v. 09CV176A

Report
&
Recommendation

PETER ACCETTA, M.D.,
SUSAN M. PETERSON, RPA-C,
ASTELLAS PHARMA US, INC.,
NOVARTIS PHAMACEUTICALS
CORPORATION,

Defendants.

This matter has been referred to the undersigned pursuant to 28 U.S.C. § 636(b)(1)(C) (Docket No. 11). The instant matter before the Court is plaintiffs' motion to remand (Docket No. 17[1]). Responses to this motion were due by May 8, 2009, and replies were due by May 13, 2009, and the Scheduling Conference in this case was adjourned pending resolution of this motion (Docket No. 21). The motion was argued on May 19, 2009, and deemed submitted (Docket No. 30 (minute entry)).

[1]In support of their motion, plaintiffs submitted their attorneys' affidavit, with exhibits (showing proofs of service of the Summons and Complaint upon all defendants, and the Answer by Dr. Peter Accetta and Susan Peterson), Docket No. 18, memorandum of law, Docket No. 19; and reply memorandum of law, Docket No. 28. In opposition, Astellas Pharma US, Inc. ("Astellas") filed its memorandum in opposition, Docket No. 23, which other defendants joined, Docket Nos. 25, 26.

BACKGROUND

This is a removed action under 28 U.S.C. §§ 1331, 1441, and 1446, by defendant Astellas Pharma US, Inc. ("Astellas") (Docket No. 1, Notice of Removal). Plaintiffs commenced a product liability action in New York State Supreme Court, Erie County, against defendants APUS, Novartis Pharmaceuticals Corporation ("Novartis"), manufacturers of two prescription drugs, Protopic® and Elidel®, respectively, used by plaintiff Jeanine Sortisio (id. Notice ¶ 2). Protopic® and Elidel® are Federal Food and Drug Administration ("FDA") approved prescription medications for the treatment of atopic dermatitis (Docket No. 23, Astellas Memo. at 2 n.1). The Complaint alleges that Jeanine Sortisio was a patient of defendants Dr. Accetta and physician's assistant Peterson (Docket No. 1, Notice of Removal, Ex., Compl. ¶¶ 2-4, 5), who prescribed Astellas' and Novartis' medications to her and she sustained Hodgkins Lymphoma (id., Compl. ¶¶ 7-8). In their first cause of action, plaintiffs allege medical malpractice against Dr. Accetta and Peterson (id., Compl. ¶¶ 1-9). The fifth cause of action alleges a loss of consortium claim by plaintiff Steven Sortisio (id., Compl. ¶¶ 27-29).

The second, third and fourth causes of action are the asserted basis for federal removal jurisdiction, according to defendants. In the second cause of action, plaintiffs allege that Astellas and Novartis negligently made, designed, and marketed their respective drugs (id., Compl. ¶ 14). Plaintiffs allege that Novartis and Astellas, and their agents, servants and employees "improperly obtained approval for the drugs known as Elidel and Protopic from the United States Food and Drug Administration" (id., Compl. ¶ 13). These drugs were allegedly defective and, as a result of the manufacturers' negligence, lead to Jeanine Sortisio sustaining serious injury, including contracting Hodgkins Lymphoma (id., Compl. ¶¶ 16-17). Repeating prior allegations (id.,

Compl. ¶¶ 18, 22), plaintiffs allege in the third cause of action that Jeanine Sortisio's injuries came from breaches of express and implied warranties from defendants (id., Compl. ¶ 19), while they allege in the fourth cause of action that defendants manufactured defective drugs and thus are liable in strict product liability (id., Compl. ¶ 23).

Each defendant answered (Docket No. 17, Pls. Atty. Aff. Ex. F (Ans. of Accetta and Peterson, filed in New York State Supreme Court); Docket Nos. 7 (Astellas Ans.), 13 (Novartis Ans.)).

Plaintiffs' Present Motion to Remand

After removal (see Docket No. 1), plaintiffs moved to remand this action to state court (Docket No. 17), noting that there is no diversity jurisdiction alleged or possible for this action (Docket No. 19, Pls. Memo. at 2). They then denied that federal question jurisdiction existed in this case (id. at 2-6), arguing that they did not allege a claim under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq., to establish federal jurisdiction (id. at 4; see also Docket No.28, Pls. Reply Memo. at 2). Plaintiffs also raised whether all defendants consented to the removal (Docket No. 19, Pls. Memo. at 6). Defendants in response, however, only addressed the threshold issue of federal question jurisdiction (Docket No. 23, Astellas Memo. at 3 n.2).

Defendants there argued that plaintiffs' second, third, and fourth causes of action are predicated upon an underlying fraud upon the FDA that led to the agency approval and release of the drugs in question, hence federal question jurisdiction exists here. Applying the standards from Grable & Sons Metal Products, Inc. v. Darue Eng'g & Mfg., 545 U.S. 308 (2005), defendants conclude that plaintiffs' otherwise state law claims implicate significant federal issues (Docket No. 23, Astellas Memo. at 4); see id., at 312, contending that plaintiffs made an

affirmative claim that defendants deceived the FDA to put these drugs into the stream of commerce, then leading to Jeanine Sortisio's injuries. They argued that the Grable standard, discussed below, was met for federal question jurisdiction to exist (id. at 3-14).

In reply, plaintiffs argued that defendants misused Grable to extend federal jurisdiction to the circumstances here (Docket No. 28, Pls. Reply at 2-3). Plaintiffs then argued that defendants misconstrued one paragraph in the Complaint to justify removal (id. at 3-4). They note that defendants have attempted to raise this basis for federal removal jurisdiction in other cases and they were rejected (id. at 5, citing Sullivan v. Novartis Pharm. Corp., 602 F. Supp. 2d 527, 533 (D.N.J. 2009); Sullivan v. Novartis Pharm. Corp., 575 F. Supp. 2d 640, 650 (D.N.J. 2009)).

DISCUSSION

I. Removal and Remand Standards

Under 28 U.S.C. § 1441, a defendant alleging original federal jurisdiction may have the pending state action removed upon notice, filing a notice to remove thirty days from service of the pleading or other paper that suggests federal court jurisdiction, 28 U.S.C. § 1446(b). All defendants must join in the removal, see id. § 1446(b); Burr ex rel. Burr v. Toyota Motor Credit Co., 478 F. Supp. 2d 432, 437 (S.D.N.Y. 2006). The plaintiffs, on any issue (aside from subject matter jurisdiction) within thirty days of the filing of the notice of removal, may then move to have that action remanded to state court, 28 U.S.C. § 1447(c).

The burden is upon the party seeking to preserve federal court removal jurisdiction (here defendants) to show that the requirements for removal were met, see 14C Charles A. Wright, Arthur R. Miller & Edward H. Cooper, Federal Practice and Procedure, § 3739, at 424 (Jurisdiction 3d ed. 1998). The Court reviews the Complaint, the Notice of Removal, and the

state court record, to determine whether removal was proper, id. at 468. Removal statutes are to be construed against removal and in favor of remand, Martropico Compania Naviera S.A. v. Perusahaan Pertambangan Minyak Dan Gas Bumi Negara (Pertamina), 428 F. Supp. 1035, 1037 (S.D.N.Y. 1977) (citing Shamrock Oil Co. v. Sheets, 313 U.S. 100, 108-09 (1941)). As noted by plaintiffs (Docket No. 19, Pls. Memo. at 4), "[t]he presence or absence of federal-question jurisdiction is governed by the 'well-pleaded complaint rule,' which provides that federal jurisdiction exists only when a federal question is presented on the face of the plaintiff's properly pleaded complaint," Caterpillar Inc. v. Williams, 482 U.S. 386, 392 (1986) (citations omitted).

II. Magistrate Judge Jurisdiction over Motion to Remand

Recently, the United States Court of Appeals for the Second Circuit held that motions to remand are dispositive under 28 U.S.C. § 636(b)(1)(A), these motions are not "pretrial matters" under that provision, and that Magistrate Judge can only render a Report & Recommendation on such motions, reversing precedent in this Court, Williams v. Beemiller, Inc., 527 F.3d 259 (2d Cir. 2008), rev'g, Williams v. Beemiller, Inc., No. 05CV836, 2006 U.S. Dist. LEXIS 69024, at *3 (W.D.N.Y. Sept. 26, 2006). Thus, a Report & Recommendation will be issued on plaintiffs' motion to remand here.

III. Application

Given defendants' response and its exclusive focus on the federal jurisdictional arguments (see Docket No. 23, Astellas Memo. at 3 n.2; but cf. id. at 14-16 (arguing that removal was procedurally proper, given timing of the notice of removal and when other defendants were served with the summons and complaint)), the Court will not consider plaintiffs' alternative procedural arguments as to whether all defendants join in the initial removal. It should be noted,

however, that all the other defendants filed papers joining in Astellas' response (see Docket Nos. 25, 26).

A state court action may be removed to federal court if the action can be brought originally in federal court, 28 U.S.C. § 1441(a), as an action "arising under the Constitution, laws, or treaties of the United States," id. § 1331; see Grable, supra, 545 U.S. at 312. Included are state law claims that "implicate significant federal issues," Grable, supra, 545 U.S. at 312, which allows federal courts to "hear claims recognized under state law that nonetheless turn on substantial questions of federal law, and thus justify resort to the experience, solicitude, and hope of uniformity that a federal forum offers on federal issues," id. Citing the example of Smith v. Kansas City Title & Trust Co., 255 U.S. 180, 199 (1921), the Grable Court held that the broadest expression of this jurisdiction would extend federal question jurisdiction to state law claims "so long as it 'appears from the [complaint] that the right to relief depends upon the construction of or application of [federal law],'" Grable, supra, 545 U.S. at 312-13. Later cases have narrowed this scope to have federal question jurisdiction exercised only in contested, substantial federal issues, "indicating a serious federal interest in claiming the advantages thought to be inherent in a federal forum," id. at 313, but subject to "a possible veto" of congressional division of jurisdictional labor between federal and state courts, id. The Grable Court then listed factors (not an "all embracing test," id. at 314) to show when a state action with an imbedded federal issue could be heard in federal court, id. "The question is does a state-law claim necessarily raise a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities," id.

The Supreme Court later noted, in Empire Healthchoice Assurance v. McVeigh, 547 U.S. 677, 701 (2006), that Grable "emphasized that it takes more than a federal element to open the 'arising under' door," and that this "arising under" jurisdiction is a "slim category that Grable exemplifies" (Docket No. 28, Pls. Reply at 3). In Empire Healthchoice, the "case concern[ed] the proper forum for reimbursement claims when a Plan beneficiary, injured in an accident, whose medical bills have been paid by the Plan administrator, recovers damages (unaided by the carrier-administrator) in a state-court tort action against a third party alleged to have caused the accident," id. at 682, raising the issue whether the insurer's reimbursement action arose under the laws of the United States for jurisdiction under § 1331, id. at 683. The insurer sought reimbursement from settlement of a state personal injury action where the insured was a federal employee who obtained coverage under benefits package governed by the Federal Employee Health Benefits Act of 1959, 5 U.S.C. §§ 8901 et seq., Empire Healthcare, supra, 547 U.S. at 700, 682-83. The Court denied federal question jurisdiction in that instance, rejecting arguments that such jurisdiction existed merely because of the source of the coverage that gave rise to that case, rejecting the United States' amicus argument that, under Grable, federal law was a necessary element of the insurer's claim hence there was federal question jurisdiction, id. at 690, 699-701. The Court distinguished Grable from the facts presented there because Grable "centered on the action of a federal agency (IRS) and its compatibility with a federal statute, the question qualified as 'substantial,' and its resolution was both dispositive of the case and would be controlling in numerous other cases," id. at 700 (quoting Grable, supra, 545 U.S. at 313). There, however, the reimbursement claim was triggered, not by federal agency action, but by private parties' state court litigation and the issue there was a factual question of what the

insurer's share of that settlement was, a "fact-bound and situation-specific" matter, id. at 700-01. The Court deemed the state courts competent to apply federal law (if necessary) to resolve the insurer's claim, id. at 701.

Next, this Court turns to the factors set forth in Grable to determine whether federal jurisdiction ought to be exercised here.

A. Raising a Federal Issue

Defendants contend that plaintiffs raised in their second, third, and fourth causes of action a federal issue, as to purported fraud upon the FDA in approving the drugs that allegedly injured Ms. Sortisio, to warrant federal jurisdiction. Plaintiffs, however, argue that the Food, Drug, and Cosmetic Act does not create a private right of action (even assuming that they were alleging such a claim), hence no federal subject matter jurisdiction exists (Docket No. 19, Pls. Memo. at 4). But, as found in Grable and its analysis of Merrill Dow Pharmaceuticals v. Thompson, 478 U.S. 804 (1986), the absence of a private right of action under a federal statute is not dispositive of federal subject matter jurisdiction, but merely is evidence relevant to the existence of that jurisdiction, 545 U.S. at 318.

Defendants contend that there is federal jurisdiction over state law claims that turn on disputed issues arising from federal statutes or regulations (No. 23, Astellas Memo. at 5), and that here plaintiffs' claims require that they establish that defendants committed fraud upon the FDA in the approval process, a claim that exists exclusively under federal law (id. at 6), Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 347, 353 (2001). They argue that these claims necessarily raise a disputed and substantial issue creating federal jurisdiction. Plaintiffs

distinguish Buckman Co. because it was a medical device case under the Medical Device Amendment to the Food, Drug, and Cosmetic Act (Docket No. 28, Pls. Reply at 5-6).

In Buckman Co., plaintiffs alleged that defendant manufacturers made fraudulent representations to the FDA as to the intended use of some bone screws and that, as a result, the devices were improperly given market clearance and were subsequently used to plaintiffs' detriment, 531 U.S. at 347. The district court dismissed the fraud-on-the-FDA claims on preemption grounds, but the Third Circuit reversed. On appeal the Buckman Co. Court reversed, holding that the state law claims were preempted by the Food, Drug, and Cosmetic Act and its amendments regarding medical devices, id.

Here, there is no federal preemption issue involved, but part of plaintiffs' claim turns upon the approval process for these drugs by a federal agency, the FDA. Therefore, plaintiffs raise a federal issue within their state law tort claims, but the next issue is whether that federal issue is substantial to warrant the exercise of federal jurisdiction.

B. Actually Disputed and Substantial Issue

Whether the substance of plaintiffs' claims (that is, whether defendants defrauded the FDA or not in approval of their respective drugs) is actually disputed is not an issue. What is now at issue is whether that dispute, as cast by plaintiffs, is substantial. Does the fact that a federal agency approved those products make the state tort claim about those products a substantial federal issue? While the approval process will delve into the federal regulatory scheme and federal agency decision-making process (cf. Docket No. 23, Astellas Memo. at 7-8), is this analysis necessary or merely tangential to plaintiffs' overall tort claims? Torts alleged by the plaintiffs are negligence, breach of warranties, and strict product liability. Each of these

claims do not necessarily require allegations that FDA was duped into allowing these drugs onto market in order to state causes of action. Part of their claim is negligent manufacture of these drugs as well as defrauding the FDA to allow them into the stream of commerce. One theory should not justify federal jurisdiction over an otherwise straightforward state common law case.

C. Congressional Balance Between Federal and State Courts

A third factor noted by the Grable Court is the jurisdictional balance set by Congress between federal and state courts in hearing cases that arise under federal laws, Grable, supra, 545 U.S. at 314, 315. Plaintiffs argue that, under the defense theory, all product liability actions where it is alleged that a federal agency approves the product and the manufacturer defrauds that agency in order to get that approval would become federal cases . Hence, all claims arising from prescription drugs (all requiring approval from the FDA before entry into the stream of commerce) become subject to removal to federal courts, overturning the balance between federal and state courts. (See Docket No. 19, Pls. Memo. at 4-5, discussing and quoting Caggiano v. Pfizer, Inc., 384 F. Supp. 2d 689, 690 (S.D.N.Y. 2005); see also Docket No. 28, Pls. Reply Memo. at 6 (noting absence of cases cited by defendants of similar pharmaceutical tort claims removed to federal court).)

This Court finds Caggiano persuasive for recommending not extending federal subject matter jurisdiction to this case. In Caggiano, the district court denied federal jurisdiction where state common law tort claims were "peppered" with federal law violations, concluding that "[t]hese contextual allegations, however, are not enough to confer federal question jurisdiction," id., where the "violation of federal law" alleged was "simply one of the multiple theories on which plaintiff may possibly prevail," id. at 691. The court had consolidated 46 state cases

removed in which plaintiffs alleged nearly identical state law claims "that defendants caused the drug Neurontin to be used for unsafe purposes and misled doctors and patients as to Neurontin's safety and efficacy," considering plaintiffs' remand motion, id. at 690. Absent special circumstances, the court in Caggiano held "there is no federal question jurisdiction over garden-variety state-law claims 'resting on federal mislabeling and other statutory violations,'" id. at 691 (quoting Grable, supra, 545 U.S. at 319).

Here, defendants are claiming federal jurisdiction over a similar garden variety New York common law tort merely on plaintiffs' single alleged theory of fraud upon the FDA leading to the torts, one of a number of theories (or part of a theory) alleged. As was found in Caggiano, supra, 384 F. Supp. 2d at 691, the "federal standards merely inform the content of classically state-law duties such as avoiding negligence and fraud," and "the factual allegations set forth in the complaint state claims under New York law regardless of whether any federal law has been violated," id. at 690. Thus, federal court consideration of these claims in this case (and in similar cases) would disturb the congressional balance of limited exercise of federal question "arising under" jurisdiction for cases that are best suited for state courts.

D. In Summary

Although the Complaint alleges fraud on the FDA as leading to plaintiffs' injuries, that claim is not sufficiently substantial to warrant federal question jurisdiction on removal. Furthermore, that theory when imposed upon these garden variety state torts (and in the absence of special circumstances not argued here) does not justify tilting the balance of federal-state court jurisdiction to have federal courts take on this (and similar) tort cases upon such an assertion of federal issues. Thus, plaintiffs' motion to remand this case should be **granted**. In light of this

recommendation, this Court has not considered plaintiffs' alternative, procedural grounds for remand.

CONCLUSION

Based upon the above, it is recommended that plaintiffs' motion to remand (Docket No. 17) be **granted**.

Pursuant to 28 U.S.C. § 636(b)(1), it is hereby ordered that this Report & Recommendation be filed with the Clerk of the Court and that the Clerk shall send a copy of the Report & Recommendation to all parties.

ANY OBJECTIONS to this Report & Recommendation must be filed with the Clerk of this Court within ten (10) days after receipt of a copy of this Report & Recommendation in accordance with 28 U.S.C. § 636(b)(1), Fed. R. Civ. P. 72(b) and W.D.N.Y. Local Civil Rule 72.3(a).

FAILURE TO FILE OBJECTIONS TO THIS REPORT & RECOMMENDATION WITHIN THE SPECIFIED TIME OR TO REQUEST AN EXTENSION OF SUCH TIME WAIVES THE RIGHT TO APPEAL ANY SUBSEQUENT DISTRICT COURT'S ORDER ADOPTING THE RECOMMENDATIONS CONTAINED HEREIN. Thomas v. Arn, 474 U.S. 140 (1985); F.D.I.C. v. Hillcrest Associates, 66 F.3d 566 (2d Cir. 1995); Wesolak v. Canadair Ltd., 838 F.2d 55 (2d Cir. 1988).

The District Court on de novo review will ordinarily refuse to consider arguments, case law and/or evidentiary material which could have been, but was not, presented to the Magistrate

Judge in the first instance. See Patterson-Leitch Co. Inc. v. Massachusetts Municipal Wholesale Electric Co., 840 F.2d 985 (1st Cir. 1988).

Finally, the parties are reminded that, pursuant to W.D.N.Y. Local Civil Rule 72.3(a)(3), "written objections shall specifically identify the portions of the proposed findings and recommendations to which objection is made and the basis for such objection and shall be supported by legal authority." **Failure to comply with the provisions of Rule 72.3(a)(3) may result in the District Court's refusal to consider the objection.**

SO ORDERED.

/s/ Hugh B. Scott

Hon. Hugh B. Scott
United States Magistrate Judge

Dated: Buffalo, New York
June 22, 2009